Claim Rejections Under 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 101

Amendments have been made to claims 5-8, 11 and 16-18 obviating these rejections. Consequently, Applicants respectfully submit that these rejections should be withdrawn.

Claim Amendments

Amendments have been made to claims 1-18 by, for example, adding the article "A" at the beginning of each claim, optionally changing Markush language, and optionally, replacing "characterized in that" with –wherein--. These and similar amendments were not made to reduce the scope of the claims, not made for statutory reasons, and not made to distinguish the prior art, but merely to conform the claims to typical U.S. patent prosecution practice.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-5, 9, 12, and 13 stand rejected as allegedly unpatentable by U.S. Pat. No. 5,536,526 (Virtanen) and claims 1-5, 12-16, and 18 stand rejected by U.S. Pat. No. 5,204,115 (Olinger). Applicants respectfully traverse these rejections.

Virtanen discloses a compressible granulate comprising about 94% to about 98% by weight of xylitol, about 1% to about 5% by weight of a polyol other than xylitol, and less than about 1% by weight of water (column 5, lines 38-42). The granulate is made, preferably, by granulating the ground xylitol with a small amount of sorbitol syrup to crystalize some of the sorbitol onto the xylitol particle surface (column 7, lines 21-25 and lines 61-63).

Olinger discloses a directly compressible, non-cariogenic xylitol granulate which comprises xylitol and a binder in the range of about 0.1% to about 5% by weight, wherein the binder is physiologically acceptable, non-cariogenic and is taken from the group consisting of polymerized reducing sugars, alkali carboxymethylcellulose and hydrogenated starch hydrolysate (column 5, line 65 to column 6, line 4). In one method, an aqueous binder solution is added to milled xylitol, and the resulting granulate is dried and screened. (Column 7, lines 8-10). Thus, it appears that Olinger adds a solution to the granulate, but does not dissolve the granulate. Olinger also discloses a directly

compressible granulate comprising a polyol such as mannitol, lactitol, sorbitol, isomalt and maltitol or a sweetener suitable for diabetic applications such as crystalline fructose and/or mixtures thereof, and a polydextrose binder present in the range of about 0.1% to about 5% by weight. (Column 7, lines 16-22).

However, to anticipate a claim, the reference must teach every element of the claim. Both these references fail to teach a tabletting aid produced by dissolving the xylitol in a solvent. Rather, these references granulate xylitol crystals. As such, they cannot anticipate the present invention.

Claim Rejections Under 35 U.S.C. §103

Claims 1-10 and 12-18 stand rejected as allegedly being unpatentable over Virtanen in view of U.S. Pat. No. 5,958,471 (Schwarz) and U.S. Patent No. 5,576,014 (Mizumoto). Applicants respectfully traverse these rejections.

Virtanen, as discussed above, granulates xylitol crystals. Schwarz relates, at least in part, to compositions obtainable by dissolving at least two polyols in water (column 2, lines 7-8). Virtanen fails to teach the desirability of dissolving the xylitol crystals in a solvent for, after subsequent processing, creating a tabletting aid. Thus, there is no motivation to combine these references. Moreover, Mizumoto fails to cure the deficiencies in the Virtanen reference because Mizumoto's dissolving compressed molding is also made by mixing or granulating various components, *see e.g* column 7, lines 19-46). Consequently, there is no *prima facie* case of obviousness.

Supererogatorily, the present invention exhibits significant and unexpected results. The Action alleges that there is no criticality in the amount of a particular component, *e.g.* xylitol, because the prior art obtains the same results desired by applicant, *i.e.* a direct compressed tablet. The Action also alleges that the amount has not been shown to provide any unusual and/or unexpected results over the applied prior art. Applicant traverses these allegations. As discussed in the present specification, comparative example 2, pure xylitol, even spray dried, does not possess the required tabletting properties. Rather, the addition of up to 10%, preferably 5-10%, of a second polyol, preferably mannitol, can achieve the desired results (see, e.g. Examples 1-4).

Consequently, Applicants respectfully submit that the present invention exhibits significant and unexpected results.

In view of the above remarks, favorable reconsideration is courteously requested. A clean copy of the amended claims is depicted in the attached APPENDIX. If there are any remaining issues which can be expedited by a telephone conference, the Examiner is courteously invited to telephone Counsel at the number indicated below.

Respectfully submitted,

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JoAnn P. Hughes
Signature

JoAnn P. Hughes
Name

APPENDIX

1. (Amended) A directly compressible tabletting aid, comprising a xylitol content of more than 90% by weight and a content of at least one other polyol of less than 10% by weight, produced by dissolving the xylitol in a solvent and spray drying or fluidized bed granulation.

2. (Amended) A directly compressible tabletting aid, according to Claim 1, wherein polyols present in addition to xylitol are selected from the group consisting of mannitol and lactitol.

3. (Twice Amended) A directly compressible tabletting aid, according to Claim 1, wherein it is obtainable by dissolving xylitol and at least one other polyol in water and spraying the resulting aqueous mixture in a stream of air at a temperature of from 120°C to 300°C.

4. (Twice Amended) A directly compressible tabletting aid, according to Claim 1, wherein it is obtainable by dissolving xylitol and at least one other polyol in water and fluidizing the resulting aqueous mixture in a stream of air at a temperature of from 30°C to 110°C.

5. (Twice Amended) A directly compressible tabletting aid according to Claim 1, wherein the xylitol and mannitol; xylitol and lactitol; or xylitol, mannitol and lactitol are employed as polyols.

6. (Amended) A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to mannitol is 90:10 to 98:2.

7. (Amended) A directly compressible tabletting aid according to Claim 5, wherein the ratio of xylitol to lactitol is 90:10 to 98:2.

8. (Amended) A directly compressible tabletting aid according to Claim 5, wherein the xylitol:mannitol:lactitol ratio is between 90:1:9 or 90:9:1 and 98:1:1.

9. (Twice Amended) A directly compressible tabletting aid according to Claim 1, wherein the water content is less than 1% by weight.

10. (Twice Amended) A process for producing a directly compressible tabletting aid according to Claim 1, comprising:

a) producing an aqueous solution of xylitol and at least one other polyol, the resulting mixture having a xylitol content of more than 90% by weight based on the total polyol content,

b1) spraying the resulting mixture in a stream of air at a temperature of from 120°C to 300°C, evaporation of the water taking place,

b2) fluidizing the resulting mixture in a stream of air at a temperature of from 30°C to 110°C, evaporation of the water taking place, and

c) isolating the tabletting aid.

11. (Twice Amended) A method for producing a shaped or unshaped polyol composition by melt extruding a directly compressible tabletting aid mixture according to Claim 1.

12. (Twice Amended) A composition or formulation comprising a directly compressible tabletting aid according to Claim 1.

13. (Twice Amended) A solid form or compact, comprising a directly compressible tabletting aid according to Claim 1.

14. (Amended) A solid form or compact according to Claim 13, comprising one or more water-insoluble and/or water-soluble additions homogeneously dispersed.

15. (Twice Amended) A solid form or compact according to Claim 13, comprising citric acid as addition.

16. (Twice Amended). A solid form or compact according to Claim 13, comprising at least one active pharmaceutical ingredient, sweetener, colorant, vitamin or trace element.

17. (Amended) A solid form or compact according to Claim 16, comprising at least one active pharmaceutical ingredient which is an analgesics or antacid.

18. (Amended) A solid form or compact according to Claim 16, comprising at least one sweetener which is acesulfame K, aspartame, saccharin, cyclamate, sucralose or neohesperidine DC.